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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	8

DATE MAILED: 05/13/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 2/28/96 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1, 17, 18, 19 are pending in the application.
   Of the above, claims 1, 17, 18 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 19 are rejected.
5. ☒ Claims 19 are objected to.
6. ☒ Claims 1, 17, 18, 19 are ~~are~~ subject to restriction or election requirement. Wew
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Part III DETAILED ACTION

Election/Restriction

1. Claims 1, 17 and 18 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 6, filed February 28, 1996.

Priority

2. If applicant desires priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application.

Claim Objections

3. Claim 19 is objected to for depending on a non-elected claim. This objection would be obviated if the claim were rewritten to include all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 19 is rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Daniels et al. (U.S. Pat. No. 3,265,579).

The claim encompasses bovine growth hormone. Daniels et al. discloses bovine growth hormone which is purified from a tissue source. (See examples 1-6, columns 2-4, especially example 6). The growth hormone disclosed in the prior art appears to be substantially the same as that of the instant claim, wherein such was isolated from bovine tissue, versus the claimed bovine growth hormone that was produced by recombinant techniques.

In the event that the bovine growth hormone of the prior art is not exactly the same as the claimed protein, it is noted that when a claimed product and product(s) disclosed or made obvious by the prior art reasonably appear to be the same, irrespective of the processes by which they are made, the burden of proof is on Applicant to demonstrate a novel or unobvious difference between the claimed product and that of the prior art (i.e., to show that the product of the prior art does not possess the same material structural and functional characteristics as the claimed product). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923.

With respect the claimed invention, it is a product-by-process claim, which is specifically addressed in the MPEP (2113):

> Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The

> patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe* 227, USPQ 964, 966 (Fed. Cir. 1985)

Although the bovine growth hormone of the prior art appears to be the same as that of the instant claim, any slight variation in purity or glycosylation would be obvious to one of ordinary skill in the art at the time the invention was made because it is always desirable to obtain proteins in their most pure form and it was well known in the art that proteins could vary in their glycosylation pattern without altering the activity or function of the protein. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, absent evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Garnette D. Draper, can be reached on (703) 308-4232. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christine Saoud, Ph.D.
May 6, 1996
CA

GARNETTE D. DRAPER
SUPERVISORY PRIMARY EXAMINER
GROUP 1800